ARNOLD & PORTER

Patenting Procedures

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February 8, 2002

The statements and opinions set forth are those of the author and do not represent the positions and viewpoints of the law firm of Arnold and Porter.

Section 112, first paragraph of Title 35 reads:

> The specifications shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any persons skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This paragraph imposes three requirements on obtaining a United States Patent: enablement, written description, and best mode.

I. The enablement requirement assures the public is actually in possession of the invention: has the specification put the invention in the hands of the public?

II. The written description requirement assures the public the inventor actually had possession of the invention when he filed the application: has the specification taught the public that the inventor had the invention in his or her hands when it was filed?

III. The best mode requirement assures the public the inventor disclosed the best method he or she knew of when the application was filed.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988):

1. The Breadth of the Claims;
2. The Nature of the Claims;
3. The State of the Prior Art;
4. The Level of Ordinary Skill;
5. The Level of Predictability of the Art;
6. The Amount of Direction Provided by the Inventor;
7. The Existence of Working Examples; and
8. The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure.

see also Enzo Biochem. v. Calgene, 188 F.3d 1362 (Fed. Cir. 1999).

According to the Supreme Court, this provision was intended:

> To put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser or other person using a machine, of his infringement of the patent; and *at the same time of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification*.

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 434 (1822).

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA.

Regents of the University of California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997).

*[*A] cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA.

Regents of the University of California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997).

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Regents of the University of California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997).

Best Mode Inquiry

1. Did the inventor have what he or she considered a best mode when the application was filed?

2. Did the specification set forth this mode?